

US-PAT-NO: 5935122

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TITLE: Dual valve, flexible expandable
sheath and method

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Abstract Text - ABTX (1):

A sheath assembly for use in introducing a catheter or other medical instrument into a vessel in the body of a patient. The sheath assembly includes an outer tubular member and an inner tubular member with a conically shaped cap at its distal end. A locking mechanism prevents advancement of the inner tubular member and associated cap in a distal direction of the vessel of the patient independent of the outer tubular member, but allows free movement of the inner tubular member in the proximal direction independent of the outer tubular member.

Brief Summary Text - BSTX (3):

Expandable access catheter assemblies have heretofore been provided to facilitate the placement and removal of diagnostic and therapeutic catheters through the vascular system. Such catheter assemblies included a flexible variable-diameter catheter body, a diameter control stylet and a flexible Y-hub. The flexible Y-hub incorporates an adjustable hemostasis valve and a side port in one branch and a diameter control stylet guide wire in another branch. A flexible variable diameter catheter body is secured to the flexible Y-hub and can be expanded between a collapsed position and an expanded position

by the stylet guide wire. Several deficiencies have been found in such a device. For example, the adjustable hemostasis valve is incapable of accepting large catheters. The flexible variable-diameter catheter body is objectionable in that it has a tendency to reduce in diameter and hold onto large-diameter catheters when it is attempted to place the same through the catheter body. In addition, the tip of the stylet guide wire catches a large-diameter catheter which causes elongation of the catheter body and reduction in its diameter to grab and prevent further advancement of the large-diameter catheter. Further, the tip of the stylet guidewire may, in certain circumstances, snag the variable-diameter catheter during removal. Additional problems with existing art involve the lack of safety features to protect against operator induced inadvertent advancement of a stylet guide wire distally into the vascular system beyond a desire distance. There is therefore a need for a new and improved large-diameter expandable sheath which will overcome these deficiencies.

Brief Summary Text - BSTX (5):

The present invention comprises a sheath assembly for use in introducing a catheter or other medical instrument into a corporeal vessel. The sheath assembly includes an elongate sheath tube formed of a flexible material having proximal and distal extremities and having a passage extending therethrough. The distal extremity of the sheath tube may have a reinforcing means for causing radial expansion of the distal extremity of the sheath tube to an expanded diameter.

Brief Summary Text - BSTX (10):

In general, it is an object of the present invention to provide an expandable sheath which can be utilized with large-diameter catheters and method for using the same. Another object of the invention is to provide a sheath of the above character which is folded longitudinally to a small diameter and which can be expanded greatly when a large-diameter catheter is to be passed through it. Another object of the invention is to provide a sheath of the above character which is provided with a backflow adapter which includes a tubular diaphragm that can be moved into an hourglass or iris-like configuration to create a fluid-tight barrier around any tubular device such as a large-diameter catheter passed through the backflow adapter and the tubular diaphragm. Another object of the invention is to provide a sheath of the above character in which a dilator can be utilized for expanding the sheath. Another object of the invention is to provide a sheath of the above character in which the backflow adaptor can be readily controlled. Other features and advantages of the present invention will become apparent from the following detailed description, taken in conjunction with the accompanying drawings, which illustrate, by way of example, the principles of the invention.

Drawing Description Text - DRTX (31):

FIG. 30 is a partial side elevational view in cross-section of an alternate embodiment of an expandable sheath tube incorporating stents and a balloon for expanding the stents.

Detailed Description Text - DETX (2):

In general, the large-diameter expandable sheath is used for introduction of a catheter into the body of a patient. It comprises an

elongate sheath tube
formed of a flexible material and having proximal and
distal extremities and
having passage therein of a predetermined maximum diameter.
The distal
extremity of the elongate sheath tube is folded
longitudinally into a smaller
diameter. A backflow adapter is secured to the proximal
extremity of the
elongate sheath tube. The backflow adapter has a central
opening therein in
registration with the passage in the sheath tube. Valve
means is disposed in
the central opening in the backflow adapter and is movable
between open and
closed positions. The valve means when in an open position
permits a catheter
to be introduced into the sheath and when closed forms a
liquid-tight seal
about the catheter extending therethrough.

Detailed Description Text - DETX (27):

The physician conducting the procedure then selects the
desired catheter or
other device which is desired to be introduced through the
expandable sheath
11. Such a device should have a diameter of 8.5
millimeters or less or which
is at least slightly less than the diameter of the bore 86.
The physician
grasps the actuator members 66 and 71 and presses the same
to operate the rack
61 to open the diaphragm or valve member 40 permitting the
physician to insert
the device as, for example, the catheter through the
expandable sheath 11. As
soon as the catheter has been advanced as far as desired,
the physician
releases the pressure on the actuator members 66 and 71
permitting the
diaphragm 40 to close around the device as, for example,
the catheter inserted
through to form a hemostatic seal about the catheter. If
it is desired to
reposition the catheter, it is merely necessary to push or
pull the catheter

and it will slide freely through the diaphragm. When it is desired to remove the catheter, the catheter need only be pulled out of the sheath 101 and the diaphragm will seal closed forming a hemostatic seal.

Detailed Description Text - DETX (28):

A silicone coating may be applied to the pleated sheath tube 12. Coating may be applied to the inner and outer surfaces prior to attachment to the backflow adapter 21. The silicone coating on the inside diameter of the sheath tube reduces the amount of force required to advance catheters and the like through the sheath tube. Additionally, the silicone coating on the outside of the sheath tube may reduce the amount of force required to advance the expandable sheath 11 into a vessel. A suitable silicone coating material is "HYDRO-SIL-D 1.0" available from TUA systems of Sarasota, Fla. Additionally, a silicone lubricant may be applied to the ring gear 36 on the primary valve assembly and the adjacent to bearing surfaces.

Detailed Description Text - DETX (30):

Next, the sheath introducer 101 is removed from the sheath assembly 11. As the distal end 106 of the sheath introducer is removed from the sheath tube 12, the secondary valve 151 is closed to form a substantially fluid tight seal between the passage 16 in the sheath tube and the secondary valve assembly 150. After the secondary diaphragm 151 is closed, the primary diaphragm 40 may be opened to fully remove the sheath introducer. Then the distal end of a catheter or other medical instrument may be inserted through the primary valve. The primary diaphragm is then closed to form a substantially fluid tight seal around the medical instrument. Next, the secondary diaphragm is opened to

allow the distal end of the medical instrument to be inserted through the secondary valve assembly, through the passage in the sheath tube and into the vessel of the patient. After the procedure has been completed, the medical instrument and the sheath assembly can be removed from the vessel and the incision which has been made in the vessel for permitting passage of the sheath assembly can be sutured.

Detailed Description Text - DETX (34):

As shown in FIGS. 27-36, the expandable sheath 11 may include a reinforced sheath tube 200. The reinforced sheath tube is similar to the elongate sheath tube 12 and similarly has proximal and distal extremities 201 and 202. A flow passage 203 is provided having a maximum diameter extending therethrough. One suitable material for the reinforced sheath is in an expanded PTFE (polytetrafluoroethylene). Such materials may be obtained from Impra of Temp, Ariz. and W. L. Gore of Flagstaff, Ariz. An example of a suitable size for a sheath tube for use with large catheter systems would include an outer diameter of approximately 0.345 inches (8.76 millimeters) with a wall thickness of 0.005 inches (0.127 millimeters) and having a length of about twenty centimeters.

Detailed Description Text - DETX (35):

The reinforced sheath tube 200 could be supported by stents, coiled wire, coiled plastic or similar means. As shown in FIG. 27, a series of self-expanding supports 210 may be placed within the sheath tube for radial expansion. Similarly, as shown in FIG. 28, a coil 211 may be attached to the outside of the sheath tube to allow for self-expansion. Alternatively, the coil support may be embedded within an inner sheath tube

212 and outer sheath tube 213, as shown in FIG. 29. The coil or expansion system may be made of a 0.012 inches (0.3 millimeters) nitinol or similar alloy wire. As shown in FIG. 30, the reinforced sheath may include balloon expandable stents 214 which may be expanded by a balloon 215 and catheter 216 or similar means.

Detailed Description Text - DETX (52):

As shown in FIG. 46, the inner tubular member 314 is then pulled in the proximal direction to abut the end cap 319 against the distal end of the outer tubular member 313 to thereby prepare the dilator assembly 312 for easy removal from the sheath 315. Finally, as depicted in FIG. 47, the dilator assembly 312 is thereafter removed from the sheath assembly 311. In this configuration, the sheath assembly 312 is used to insert catheters and other instruments into a patient's vascular system.